



SAS:sas 07/13/09 4239-66899-01 draft declaration (2).doc E-153-2002/0-US-03Attorney Reference Number 4239-66899-01  
Application Number 10/666,022

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of:** Klinman et al.

**SUBMITTED VIA EFS ON**

**Application No.** 10/666,022

**Filed:** September 17, 2003

**Confirmation No.** 7954

**For:** METHOD OF TREATING AND  
PREVENTING INFECTIONS IN  
IMMUNOCOMPROMISED SUBJECTS  
WITH IMMUNOSTIMULATORY CPG  
OLIGONUCLEOTIDES

**Examiner:** Michelle S. Horning

**Art Unit:** 1648

**Attorney Reference No.** 4239-66899-01

SUBMITTED VIA THE ELECTRONIC FILING SYSTEM  
COMMISSIONER FOR PATENTS

**DECLARATION OF DENNIS M. KLINMAN AND DANIELA VERTHELYI  
UNDER 37 C.F.R. § 1.132**

1. We, Dennis M. Klinman and Daniela Verthelyi are the inventors of the above-identified patent application.
2. It is our understanding that Claims 1, 8-17 and 21 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Klinman et al., (U.S. Patent No. 6,977,245). We are inventors of the work disclosed and claimed in Klinman et al.
3. In making the rejection, the Office action refers to specific paragraph at column 7, lines 48-60 of U.S. Patent No. 6,977,245 (Klinman et al.) This paragraph is a definition that and is set forth below:

**"Immune system deficiency:** A disease or disorder in which the subject's immune system is not functioning in normal capacity or in which it would be useful to boost a subject's immune response. Immune system deficiencies include those diseases or disorders in which the immune system is not functioning at normal capacity, or in which it would be useful to boost the immune system response. In one specific, non-limiting example, a subject with an immune system deficiency has a tumor or cancer (e.g. tumors of the brain, lung (e.g. small cell and non-small cell), ovary, breast, prostate, colon, as well as other carcinomas and sarcomas)."

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This subject matter is not claimed in Klinman et al.

4. We conceived any and all subject matter disclosed in U.S. Patent No. 6,977,245 (Klinman et al.) that relates to immune system deficiencies or immunocompromised subjects. In particular we conceived of a method of increasing an immune response to an opportunistic infection in an immunocompromised subject by administering an immunostimulatory D oligodeoxynucleotide (ODN) as claimed in the above-referenced application. Thus, this definition found at column 7, lines 48-60 of U.S. Patent No. 6,977,245, and any other information in U.S. Patent No. 6,977,245 (Klinman et al.) that describes immune system deficiencies or immunocompromised subjects is own work alone. To the extent that U.S. Patent No. 6,977,245 (Klinman et al.) is considered to disclose method of treating a immunocompromised subject, or to induce an immune response to an infection in these subjects, we and not the other co-inventors of U.S. Patent No. 6,977,245 (Klinman et al.) invented this subject matter. We are also the inventors of the methods claimed in the above-referenced application.
5. We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

\_\_\_\_\_  
Dennis M. Klinman

\_\_\_\_\_  
Daniela Verthelyi

\_\_\_\_\_  
Date

7-13-09  
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Date